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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,903	07/11/2000	Heather J. Jordan	0942.4450001 (IVGN 187.1	1446
05.02	7590 02/02/2007 CORPORATION		EXAMINER	
C/O INTELLEVATE P.O. BOX 52050			SISSON, BRADLEY L	
MINNEAPOLI	•		ART UNIT	PAPER NUMBER
			1634	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MO	3 MONTHS 02/02/2007 PAPER		ER	

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)
	09/613,903	JORDAN, HEATHER J.
Office Action Summary	Examiner	Art Unit
·	Bradley L. Sisson	1634
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the	correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statut.  - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	OATE OF THIS COMMUNICATION  136(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDON	ON. timely filed om the mailing date of this communication. NED (35 U.S.C. § 133).
Status	· ·	
<ul> <li>1) Responsive to communication(s) filed on 22 / 22 / 22 / 22 / 22 / 22 / 22 / 2</li></ul>	s action is non-final. ance except for formal matters, p	
Disposition of Claims		
4) ☐ Claim(s) 65-127 and 129-139 is/are pending i 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 65-127 129-139 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	awn from consideration.	
Application Papers		
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acceptable and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E	cepted or b) objected to by the drawing(s) be held in abeyance. Setion is required if the drawing(s) is c	ee 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documen 2. Certified copies of the priority documen 3. Copies of the certified copies of the priority application from the International Burea * See the attached detailed Office action for a list	ts have been received. ts have been received in Applica prity documents have been recei nu (PCT Rule 17.2(a)).	ation No ved in this National Stage
Attachment(s)    Notice of References Cited (PTO-892)   Notice of Draftsperson's Patent Drawing Review (PTO-948)   Information Disclosure Statement(s) (PTO/SB/08)   Paper No(s)/Mail Date	4) Interview Summa Paper No(s)/Mail 5) Notice of Informal 6) Other:	Date

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#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 November 2006 has been entered.

### Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 65-127 and 129-139 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.
- 4. Claim 65, and claims 55-84 and 130-134, which depend therefrom, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 65 is indefinite with respect to just what constitutes the metes and bounds of "substantially equal intensity." Claims 55-84 and 130-134, which depend from said claim 65, fail to overcome this issue and are similarly rejected.

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5. Claim 85, and claims 86-104 and 125-129, which depend therefrom, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 85 is indefinite with respect to just what constitutes the metes and bounds of the phrase "substantially equal relative mass." Claim 85 is also indefinite as a result of using the expression of nucleotides in place of a unit of mass. Consequently, it is not clear just what the mass of any one rung in the ladder is to have, much less how it is to vary from one rung to another of the ladder.

- 6. Claims 86-104 and 125-129, which depend from said claim 85 fail to overcome this issue and are similarly rejected.
- Claim 105, and claims 106-125 and 130-137, which depend therefrom, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 105 is indefinite as to jut what constitutes the metes and bounds of "substantially equivalent," and how this relates to both mass (even when as here no unit of mass is provided), as well as how it relates to copy number of fragments of nucleic acid that are to comprise each rung of a nucleic acid ladder, when the nucleic acid fragments may comprise labels and/or modified nucleotides.
- 8. Claims 106-124 and 130-139, which depend from claim 105, ail to overcome this issue and are similarly rejected.
- 9. Claim 101 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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- 10. Claim 102 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
- 11. Claim 121 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
- 12. Claim 122 recites the limitation "said detectable label" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
- 13. Claim 125 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.
- 14. Claim 126 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.
- 15. Claim 127 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.
- 16. Claim 129 recites the limitation "the relative mass" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 85, from which it depends, has support for "substantially equal relative mass," which has also been rejected under 35 USC 112, second paragraph, for being indefinite.

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17. Claim 129 is indefinite with respect to what constitutes "about the same."

18. Claim 134 is indefinite with respect to what constitutes the metes and bounds of "about

the same intensity."

### Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (f) he did not himself invent the subject matter sought to be patented.
- 20. Claims 65-82, 85-102, 105-122, 125-127 and 129-139 are rejected under 35
- U.S.C. 102(b) as being anticipated by US Patent 5,316,908 (Carlson et al.).
- 21. Carlson et al., Fig. 1, disclose a nucleic acid ladder that meets the size, relative mass, and intensity requirements of claims 65-82, 85-102, 105-122, 125-127 and 129-139.
- While claims 81, 82, 101, 102, 121, and 122 all recite detectable label to be used when performing the detection, however, the claims are not drawn to a method but to a product, which does not require the detectable label to be present.
- 23. Claims 65-82, 85-102, 105-122, 125-127 and 129-139 are rejected under 35
- U.S.C. 102(f) because the applicant did not invent the claimed subject matter. It is noted that the assignee of the '908 patent and the instant application at the time of filing are one and the same, yet the inventorship is different.

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# Claim Rejections - 35 USC § 103

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- 24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 25. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 26. Claims 83, 84, 103, 104, 123, and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,316,908 (Carlson et al.) in view of US Patent 5,527,670 (Stanley).
- 27. See above for the basis of the rejection as it relates to the disclosure of Carlson et al.
- 28. Carlson et al., while teaching of the staining of a gel through the use of a dye, and of conducting gel electrophoresis, has not been found to disclose the addition of a dye such as bromophenol blue.
- 29. Stanley, column 10, second paragraph, discloses the addition of a loading dye, which comprises bromophenol blue, to a mixture of oligonucleotides that are to be separated via gel electrophoresis.

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30. It would have been obvious to one of ordinary skill in the art to have incorporated the use of a dye such as bromophenol blue, into the nucleic acid ladder composition of Carlson et al., as such would have facilitated the ready identification of the sample having been loaded into the gel and of its migration into the gel matrix. In view of the well-developed nature of gel electrophoresis, said artisan would have had a most reasonable expectation of success.

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For the above reasons, and in the absence of convincing evidence to the contrary, claims 83, 84, 103, 104, 123, and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,316,908 (Carlson et al.) in view of US Patent 5,527,670 (Stanley).

#### Conclusion

- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
- 33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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34. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bradley L. Sisson Primary Examiner

B. Z. Sinon

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